

## REMARKS

Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 37-46 are pending and under examination in the application. By the above amendments, claims 37, 41, 44 and 46 have been amended and claims 38-39 and 42-43 have been canceled. The above amendments are not to be construed as acquiescence to the stated grounds for rejection and are made without prejudice to prosecution of any subject matter modified or removed by the amendments in a related divisional, continuation and/or continuation-in-part application.

### *Priority*

The Examiner asserts that claims 39-40 and 43-46 are entitled to a priority date of December 27, 2001, on the basis that the subject matter of these claims is not adequately supported by provisional applications to which priority has been claimed. Applicants will address the issue of priority upon arriving at allowable subject matter.

### *Rejections Under 35 U.S.C. § 112*

Claims 37-46 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking an enabling disclosure. More particularly, the Examiner asserts that the specification, while being enabling for a composition for determining the presence of breast cancer, does not reasonably provide enablement for a composition for determining any and all cancers using the elected sequences.

For purposes of clarity and to advance prosecution of the subject application, Applicants have amended claims 37 and 41 such that the claims now recite a composition for detecting a *breast* cancer cell in a biological sample. As noted by the Examiner, this subject matter is fully enabled by the specification as originally filed. Reconsideration is respectfully requested.

### *Rejections Under 35 U.S.C. § 102*

Claims 37-38 and 41-42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Harada *et al.* (PNAS USA, Vol. 90, pgs. 11312-11316, 1993). According to the Examiner, Harada *et al.* teach a composition comprising a first oligonucleotide and a second

oligonucleotide, wherein the first oligonucleotide and the second oligonucleotide hybridize to a first polynucleotide and a second oligonucleotide respectively; wherein the first polynucleotide is unrelated to the second oligonucleotide and wherein the first and second polynucleotides are complementary tissue-specific polynucleotides of the cancer to be detected.

Applicants respectfully traverse. By the above amendment, the claimed invention has been focused on the elected sequences of SEQ ID NOs: 7 and 75. The claims are thus drawn to compositions for the detection of breast cancer cells in a biological sample, said compositions comprising an oligonucleotide specific for SEQ ID NO: 7 and an oligonucleotide specific for SEQ ID NO: 75. Applicants respectfully submit that Harada *et al.* does not describe SEQ ID NO: 7 or SEQ ID NO: 75, much less that compositions which comprise oligonucleotides specific for these two markers would provide advantages in the context of breast cancer detection. Accordingly, the currently claimed invention is submitted to be novel over Harada *et al.* Reconsideration is respectfully requested.

Claims 37-38 and 41-42 also stand rejected under 35 U.S.C. § 102(b) as being anticipated by Frudakis *et al.* (IDS, AK). According to the Examiner, Frudakis *et al.* teach a composition comprising a first oligonucleotide and a second oligonucleotide, wherein the first oligonucleotide and the second oligonucleotide hybridize to a first polynucleotide and a second oligonucleotide respectively; wherein the first polynucleotide is unrelated to the second oligonucleotide and wherein the first and second polynucleotides are complementary tissue-specific polynucleotides of the cancer to be detected.

Applicants respectfully traverse. By the above amendment, the claimed invention has been focused on the elected sequences of SEQ ID NOs: 7 and 75. The claims are thus drawn to compositions for the detection of breast cancer cells in a biological sample, said compositions comprising an oligonucleotide specific for SEQ ID NO: 7 and an oligonucleotide specific for SEQ ID NO: 75. Applicants respectfully submit that Frudakis *et al.* does not describe SEQ ID NO: 7 or SEQ ID NO: 75, much less that compositions which comprise oligonucleotides specific for these two markers would provide advantages in the context of breast cancer detection. Accordingly, the currently claimed invention is submitted to be novel over Frudakis *et al.* Reconsideration is respectfully requested.

Application No. 10/033,527  
Reply to Office Action dated November 15, 2005

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are believed to be in condition for allowance. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,  
SEED Intellectual Property Law Group PLLC



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